

The Agency's Quality System and the Draft Action Plan

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by

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Attachment 1 - Summary of Elements of the EPA Quality System

1. Introduction

The contents of this document represent the thoughts of John Maney, solely, and are not intended to represent those of the USEPA nor members of the Metal Assessment Subcommittee. This document has been written to offer suggested roles for the Agency's Quality System in the Action Plan, the Framework for Metals Assessment and the Guidance for Characterizing and ranking Metals.

2. The Agency's Quality System

For some time the EPA has recognized that "Quality" of services or products (as defined by the usefulness to the user) is an attribute that is independent of production pressures (e.g., budgets, scheduling, resource limitation) and established a quality system to oversee and make impartial decisions regarding quality.

The Agency has based its quality oversight function on a consensus standard ANSI/ASQC E4-1994. The Agency's Quality System (QS) is described in OSWER Directive 5360.1 A2 and the Agency's Quality Manual. The Agency's QS is applicable to all EPA organizational units conducting environmental programs that collect, evaluate or use environmental data. (Environmental data are any measurements or information that describe environmental processes or conditions, or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.)

The scope of the Agency's QS is quite encompassing and consist of three levels, the Policy Level, the Organizational Level and the Project Level. The QS is explained in more detail in documents available on the internet (<http://www.epa.gov/quality1/>) and has been summarized by Kathleen White of the SAB (Attachment 1).

3. OMB Guidelines on Information Quality

3.1 Regulatory Background

The Office of Management and Budget (OMB) has authored guidelines on Information quality (<http://www.whitehouse.gov/omb/fedreg/reproducible.html>) in response to the Data Quality Act (Section 515 of Public Law 106-554; HR 5658).

These guidelines are perceived as having the potential for changing the way business is done by Federal Agencies and those who wish to influence decision-making processes within the Federal government.

These guidelines require almost all Federal Agencies (i.e., all Agencies subject to the Paperwork Reduction Act) to;

- implement guidelines by 10/1/02 to ensure information quality
- establish a process for reviewing quality before information is disseminated
- establish corrective mechanisms for non-compliant information & for complaints from other parties regarding information
- produce periodic reports to OMB on the number and nature of complaints regarding accuracy of information and how these complaints were handled

3.2 Definitions

The OMB guidelines discusses three tiers of information that are subjected to these guidelines

Information – “any communication or representation of knowledge such as facts or data”

Influential Information - means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions

Risk - Information regarding “analysis of risks to human health, safety and the environment”

The above information types are subject to the OMB Quality Guidelines on and after 10/1/02, if the information is “disseminated”

Dissemination – “agency initiated or sponsored distribution of information to the public”

Limited types of information (e.g., press releases, scientific journal articles, material in response to subpoenas) are not subject to these guidelines. However all non-excluded information released after 10/1/02 are subject to these guidelines even if the information was generated prior to that date. Also when an upper-tier document such as a policy or a *risk assessment* is disseminated, at the time of dissemination, all underlying information and data upon which that upper-tier document is based, are also deemed disseminated and subject to the quality guidelines.

Disseminated information that is not excluded must comply with the following OMB quality attributes,

Integrity - refers to the security of information – protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

The integrity attribute has a focus on electronic security of data, which is important in these days of the Internet and hackers. However, the definition does not address the more common sources of negative impacts on data integrity such as mishaps due to poor communications or loss of qualifying field, lab or data handling information that influence data use, when known.

Utility - refers to the usefulness of the information to its intended users, including the public.

This attribute, as presented in the guidelines, is an understatement of the complex issue of data usability. Environmental data collection usually involves the implementation of multi-disciplinary details and assessing compliance with this attribute is a significant task that is not addressed in the guidelines.

Objectivity - involves two distinct elements, presentation and substance. Objectivity includes whether disseminated information is being presented in an accurate, clear, complete and unbiased manner. --- In addition, “objectivity” involves a focus on ensuring accurate, reliable and unbiased information

Regarding the “Objectivity” attribute, quality information is not enough – the presentation also needs to be of sufficient quality. Regarding the definition of “Objectivity”;

- Terms such as “accurate” & “unbiased” are not defined and are not compatible with their scientific use
- “Reliability” is not defined. It is likely to be interpreted in a legalistic manner¹
- Peer reviewed information is presumed “Objective” until a defensible argument to the contrary is made

Objectivity is evaluated with a graded approach with these guidelines requiring that “influential” and “risk” information must also be transparent and reproducible;

¹ Reliability is defined by the Federal Rules of Evidence as interpreted by case law (Daubert)

Transparency - means that the method of information generation is described such that an independent party could reproduce it

Reproducibility - means that the information is capable² of being substantially reproduced subject to an acceptable degree of imprecision.

In addition, to comply with the objectivity attribute, risk information must conform with the Safe Drinking Water Act (SDWA) quality principles³, which can be summarized as follows,

- use of best available, peer-reviewed science
- supporting studies must be conducted in accordance with sound & objective scientific practices
- data must be collected by accepted or best available methods
- presentation of risk effects must be comprehensive, informative and understandable
- the presentation must specify population at risk, expected risk, upper and lower bounds, uncertainty, supporting & non-supporting studies, and how inconsistencies between the non-supporting studies and the risk findings were reconciled

3.3 Applying the OMB Guidelines

The OMB guidelines allow for a graded approach (i.e., more important information must meet higher standards of quality). This graded approach is captured in figure 1, which can be used to summarize how the guidelines are applied. For example, whenever there is a communication or preferably when a communication is planned, the agency has to decide if the communication contains information (i.e., knowledge such as data or facts).

In the hopeful event, that all communications contain information, then the next question is whether the communication is intended for dissemination to the public. (If the dissemination is internal to the Agency, then the guidelines do not apply.)

Next, determine if the information intended for release to the public is excluded from coverage by the OMB quality guidelines (i.e., press releases, archival records, public filings, subpoenas, adjudicative processes, or opinions of employees, when labeled as such)

If not excluded then a determination has to be made as to whether the information is influential. If it is not influential information then the information must comply with the Integrity, Objectivity and Utility (IOU) requirements.

If the information is influential and not risk information, then it has to comply with the IOU attributes as well as the attributes of transparency and reproducibility. If the information is risk information then it has to comply with the SDWA quality principles in addition to the IOU, transparency and reproducibility attributes.

3.4 Discussion

² Not all influential information has to be reproduced by the Agency prior to dissemination, but it has to be capable of being reproduced. That is, documentation needs to be sufficient enough and the information of sufficient quality such that a second or third party to reproduce the work within an acceptable degree of imprecision.

³ 1996 Amendments to the Safe Drinking Water Act

The OMB Information Quality guidelines and the Agency's response to these guidelines need to be understood before the Framework and guidance documents can be finalized. Once the Agency has finalized its response to the guidelines, the Agency needs to assign authority and responsibility and develop procedures for its implementation. These authorities, responsibilities and procedures need to be reflected in the framework and guidance documents.

The Agency, in its proposed response to the OMB guidelines, "decided to adapt the SDWA principles with minimal changes for use with all human risk assessments", while the agency sought public comment regarding the application of the SDWA principles to environmental and safety risks. The Agency needs to define what it means when it indicates "minimal changes" to application of human risk and what the Agency's final position will be regarding environmental and safety risks. These are questions that will need to be answered before the framework and guidance documents can be completed.

Discussions in professional journals and periodicals indicate that a large minority if not a majority opinion, among attorneys following the OMB guidelines, is that the guidelines will have a significant impact on how Federal Agencies employ science in its policies and rule-making. It is key that the impact of these guidelines be addressed in the Framework and guidance documents so that agency positions on risk and supporting information will be scientifically defensible and can withstand legal scrutiny. For example, future guidance must emphasize documentation of the entire risk assessment and supporting information so that the assessment is suitably transparent and can be reproduced by a second or third party.

COMPLIANCE WITH OMB GUIDELINES

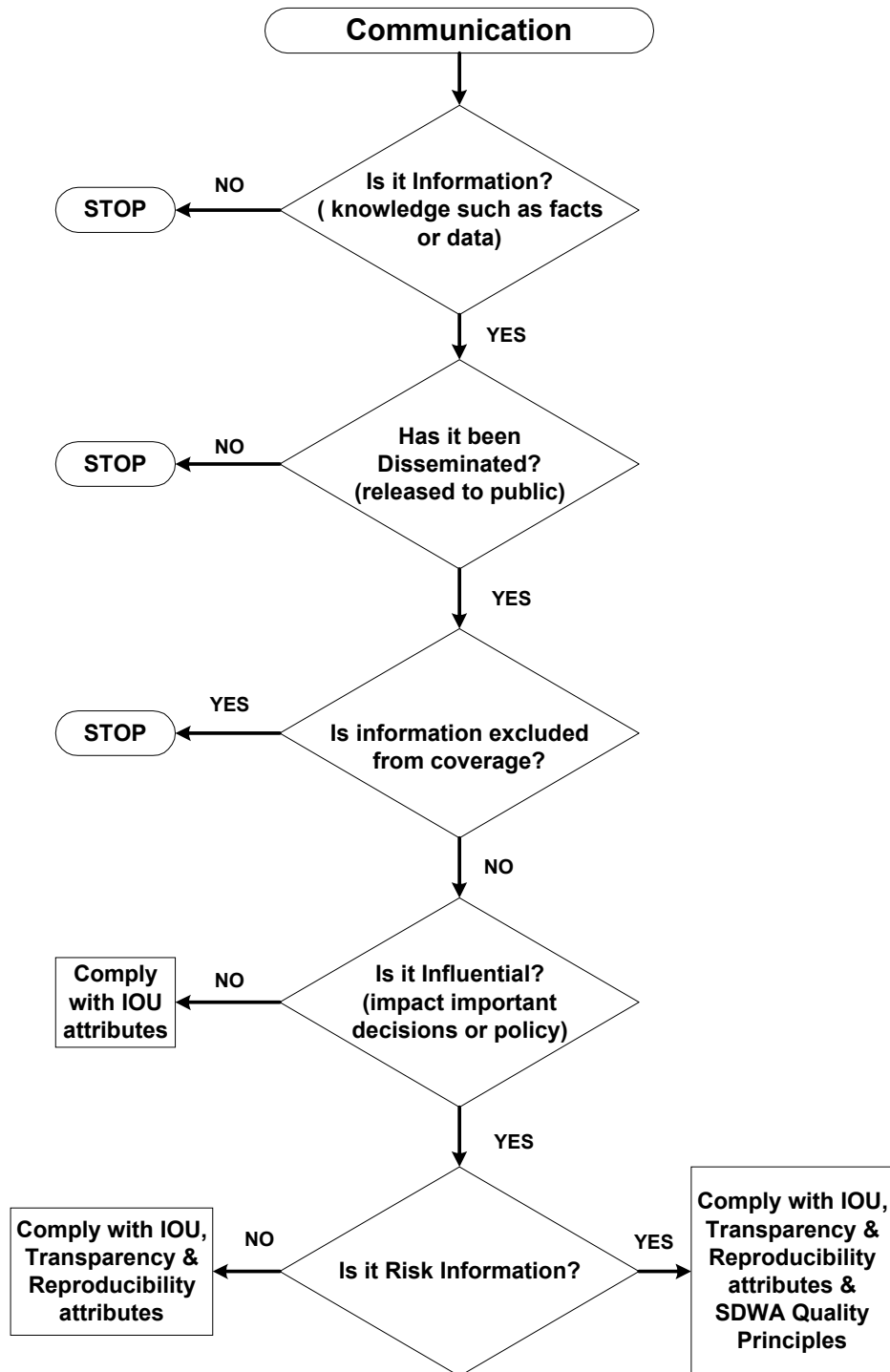


FIGURE 1

4. Goals And Intended Audience

As indicated above, quality is an attribute that is evaluated, in terms of the intended use of the product or service, by the consumer. Thus it is very important to understand the intended use and the targeted consumer (i.e., the audience for the Framework and guidance documents).

It is arguable that the responses to the eight charge questions presented to the Subcommittee could vary significantly with a change in the intended audience or a change in the goals of the Framework or guidance documents.

4.1 Goals

The Metals Action Plan (MAP) was written to facilitate and direct the authoring of two documents;

1. Framework for Metals Assessment
2. Guidance for Characterizing and Ranking Metals

The *goal of MAP* as stated in its Executive Summary is to establish a process for developing guidance that will assure;

1. a consistent application of scientific principles for assessing hazard and risk for metals
2. state-of-the-science application of methods and data
3. a transparent process (i.e. articulating assumptions and uncertainties), and
4. the flexibility to address program-specific issues.

The *goal of the Framework* document, as extracted from the MAP (pages 34 and 35), are to;

1. patterned after the Ecological Risk Assessment Framework
2. develop Cross-Agency guidance that focuses on the special attributes and behavior of metals and metal compounds and will supplement existing guidance
3. lay out key scientific principles and issues that need to be addressed in assessing the hazards and risk of metals;
4. develop conceptual models for different scenarios and types of environmental decisions;
5. identify the kinds of scientific information, approaches, methods, and models that are available for differentiating among metals as to their human health and ecological risk.
6. include metal-by-metal considerations that will vary depending on level of scientific assessment needed and scope of regulatory activity

The *goal of the Guidance* Document as extracted from the MAP (pages 34 and 35) are to;

1. document cross-agency guidance for applying the principles described in the Framework Document
2. provide the tools and specific guidance for characterizing and assessing the hazards and risks of metals
3. address critical needs identified by the stakeholders
4. be applicable to situations of priority setting, categorization, and similar activities.

The MAP also discusses a three-tiered approach, which sheds light on the breadth of issues that have to be addressed to meet the above goals.

The majority of the eight SAB charge questions speak to the appropriateness of the specified goals. Assuming that the above lists accurately capture the goals, then the Subcommittee charge, in part, is to determine if the proposed structure of the Framework and guidance documents will achieve these goals.

It may be helpful for the Subcommittee to ask the Agency to summarize the goals for each of the two proposed documents in terms of the depth of technical detail the Agency anticipates for these documents. Does the Agency foresee the framework document reflect the same level of detail as the Ecological Assessment Framework document⁴? More? Less? What comparable level of detail will the Guidance document contain?

4.2 Audience

Although not specifically stated, the audience for the MAP is those who will author the Framework and guidance documents and the interested public. The targeted audience for the Framework document is primarily risk assessors with a secondary audience being stakeholders and the public (Page 35). The audience for the guidance is for those who are involved in the hazard ranking and characterization of metals (page 38), although the specific audience is not defined.

It may be helpful to have the Agency expand upon the audience it perceives for both documents. For example who are the “Stakeholders “ for the Framework document? The framework document will have to be written differently based on who the stakeholders are (Sophisticated decision makers with a technical background? less technical senior management with a policy bent? the Public? What is the range of stakeholder expertise?). For instance, an executive summary and/or introductory discussions may be appropriate if some of the targeted stakeholders lack a technical background.

It would be difficult to evaluate the MAP and associated documents without a solid understanding of the intended audience. Upon understanding the Agency’s perception, the Subcommittee may want to comment on the appropriateness of the proposed audience.

5. The Role of the QS in the MAP and Subsequent Guidance

Risk assessments are complex multi-disciplinary tasks, whose success is dependent upon the implementation of numerous details in an exacting manner. How these underlying details are chosen and implemented will determine the type and magnitude of errors and the certainty in the final assessment.

Source term concentrations are often assumed to be accurate, however they should be questioned and evaluated in terms of the associated sampling, analytical and quality assurance program. For example, the heterogeneity of the population being sampled and the act of collecting samples is estimated to be the source of as much as 90% of the data variability⁵. After the sample is submitted to the laboratory for analysis, subsampling is required. One study found that subsampling accuracy was at least two orders of magnitude worse than the accuracy of the analytical method⁶. A study of 49 data sets for metals in soil that were analyzed by both contract laboratories and a QA laboratory, determined that over 10% of the data were less than 40% or greater than 250% of the referee value⁷.

⁴ Is the Ecological Assessment Framework document available to the Subcommittee?

⁵ Crumblin, D.M.: Applying the Concept of Effective Data to Environmental Analyses for contaminated Sites. October 2001, EPA 542-R-01-013

⁶ Gerlach, R.W., et al: “Gy sampling theory in environmental studies - 1. Assessing soil splitting protocols, J. Chemometrics 2002, 16: 321-328

⁷ Grant, c.l. et al: Comparison of Environmental Chemical Results of Split Samples Analyzed in Different Laboratories, Journal of AOAC International Vol. 80, No.5, 1997, 1129-1138

Pitfalls in the statistical treatment of environmental data have been discussed⁸, while others questioned the basis of ecological benchmarks⁹, proposed methods to evaluate the uncertainty of assessments¹⁰, discovered that physical-chemical factors, used in models, spanned 2 to 4 orders of magnitude for the same property for the same compound¹¹ and argued that a specific risk had been overstated a thousand fold¹².

While the details of the above concerns can be debated, there is widespread appreciation for the uncertainty and quality of risk assessments, in large part due to their inherent and multi-disciplinary complexities. These complexities and the potential error associated with each underlying detail demands that risk assessments be performed under the auspices of a Quality System and that the need and role of the Quality System be appropriately discussed in the framework and guidance documents. The discussion should avoid the temptation to focus solely on measurable errors (i.e., random and systematic errors that are detected through the use of quality controls such as replicates and blanks) at the expense of non-measurable errors (incorrect constants, assumptions and blunders), which are controlled through the use of quality assurance procedures.

If the Subcommittee wants to further pursue the issue of Quality Systems and how they may be applicable to risk assessments, a presentation to the Subcommittee by a member of the Agency's Quality Staff may be useful.

6. Findings

This section summarizes findings regarding application of the Agency's Quality System to the MAP and subsequent Framework and Guidance Documents.

6.1 Omissions

The following terms are not included or discussed in the MAP

- Quality System
- Quality controls
- Quality Assurance Procedures
- OMB Information Quality Guidelines
- SDWA Quality Principles
- Integrity
- Objectivity
- Utility
- Reproducibility
- Council on Regulatory Modeling (CREM)
- Accuracy
- Bias
- Precision
- Error
- Systematic planning

⁸ Sutherland, R.A, Analysis and commentary on Statistical Methods and Pitfalls in Environmental Data Analysis by Yue Rong, Environmental Forensic

⁹ Durda, J.L. et al; Data Quality Evaluation of Toxicological Studies Used to Derive Ecological Benchmarks, Human and Ecological Risk Assessment: Vol. 6 No. 5, 747-765

¹⁰ Vorhees, D.J. et al; An Evaluation of Sources of Uncertainty in a Dredged Material Assessment; , Human and Ecological Risk Assessment: Vol. 8 No. 2, 369-389

¹¹ Pontolillo, J et al; The Search for Reliable Aqueous Solubility (S_w) and Octanol-Water Partition Coefficients (K_{ow}) Data for Hydrophobic Organic Compounds: DDT and DDE as a Case Study, USGS, Water Resources Investigation Report 01-4201

¹² Cochran, R.C.; Appraisal of Risks from Nonoccupational Exposure to Chlorryrifos, Regulatory Toxicology and Pharmacology 2002, 35, 105-121

It is a fair extrapolation that if these key topics are not discussed in the MAP, then there is a significant probability that some of these issues will not be discussed in the subsequent framework and guidance documents.

Transparency is mentioned as a goal but how transparency and the necessary documentation needed to achieve reproducibility in risk assessments is not discussed.

Peer review is discussed in terms of the writing process for the MAP, framework and guidance documents, but the role of peer reviews in future risk assessments is not discussed. Peer reviews are a critical mechanism for achieving compliance with the Agency's Quality System and the OMB Information guidelines.

The Office of Management & Budget Guidelines on Information Quality are not discussed, which is a significant omission. Lack of compliance with OMB guidelines is likely to impact the ability of the Agency to employ metal risk assessments and to achieve its mission.

The MAP does discuss "uncertainty", which reflects the authors' understanding of the importance of quality. However, if the MAP is not specific and thorough in detailing the important role of quality oversight, then the quality of any estimation of uncertainty and risk assessment done as per the MAP/Framework/Guidance documents will be unknown and questionable.

Since the MAP indicates that the proposed documents will promote the use of specific models, it is important that the Agency has documented the applicability of the models to the range of potential uses. The Agency should consult with CREM, the SAB and other areas of expertise within and without to ensure that there are quality assurance procedures that addresses the quality of source terms, model inputs, model sensitivity and ground-truthing and the quality of outputs in terms of the decisions that need to be made.

The MAP, while not specifying authorities and responsibilities, should discuss the need and mechanism for assigning authority and responsibility for oversight of quality issues to an appropriate expert or team of multi-disciplinary experts who are independent of a given risk assessment (e.g., a Quality Assurance Officer).

The commendable Agency-wide approach to metal risk assessments requires that the Agency's Quality System should be reviewed and possibly modified at the Policy, Organizational and Project levels.

6.2 Systematic Planning

Systematic planning is the optimum method for ensuring that metals risk assessments are applied consistently and successfully across the Agency. Risk assessments are complex, multi-disciplinary undertakings that require planning by the appropriate team of experts and stakeholders. This complexity is not unlike that encountered during the design of environmental data collection activities, for which the Agency has successfully design a systematic planning process called the Data Quality Objective (DQO) Planning Process. This process has been documented in guidance (<http://www.epa.gov/quality/qs-docs/g4-final.pdf>) and its use is required for environmental data operations by Section 3.3.8 of the Agency's Quality System (http://www.epa.gov/quality/qa_docs.html). The concluding product of the DQO planning process is a Quality Assurance Project Plan (QAPP) that describes how the data operation will be implemented (<http://www.epa.gov/quality/qs-docs/g5-final.pdf>). It is EPA policy that all work funded by EPA in which environmental data will be collected, evaluated, used, or reported (including the use of existing data and modeling), or which involves the design, construction, and operation of environmental technology, must have approved QAPPs. The Agency has developed draft guidance for "Quality Assurance Project Plans for Modeling" (EPA QA/G-5M) (<http://www.epa.gov/quality/qs-docs/g5m-prd.pdf>), which is designed for model development and model application.

The strength of the DQO planning process is that it encourages the planners to confront the underlying and multidisciplinary details and the associated complexity upfront in the planning phase, which increases the likelihood that data/physical-chemical constants of sufficient quality will be employed in the assessment, that the appropriate models and tools will be employed and that the risk assessment will be usable, comply with OMB information Quality guidelines and withstand scrutiny. It should be noted that when a systematic planning process is not followed, decisions are still made regarding issues such as; source terms, model inputs and assumptions, but lacking a planning structure these decisions may be made by default, by a modeler or in the field by personnel who may not be familiar with the objectives of the assessment.

The MAP (page 34) indicates that the Metals Framework document will be patterned after the Ecological Risk Assessment framework. While this document could not be located for this review the associated Ecological Risk Assessment Guidelines were perused and found to contain many of the issues that would need to be addressed during planning, but the issues were presented in the form of questions. A more structured planning process would promote greater consistency across risk assessments.

In summary, adding structure to the planning phase of risk assessments is likely to be the best insurance for consistency and ensuring quality of Agency-wide risk assessments. Systematic planning increases the likelihood that critical issues will be given a level of attention, which reflects their importance. Thus, it is suggested that the Framework and guidance documents describe and promote a systematic planning process and the use of QAPPs that mirror the issues raised in the guidance cited above.

Attachment 1

Summary of Elements of the EPA Quality System

[Kathleen White, SAB]

The Agency's quality **policy** is consistent with ANSI E-4 and is defined in EPA Order 5360.1, the Quality Manual and the organizational components designed for policy implementation as described by the Agency's **Quality System** (EPA QA/G-0). The quality system provides the framework for planning, implementing, and assessing work performed by the organization for carrying out required quality assurance and quality control.

EPA has a comprehensive system of tools for managing its data collection and use activities to assure data quality. The **management tools** used in the organizational level of the EPA Quality System include Quality Management Plans and Management System Reviews. The **technical tools** used in the project level of the EPA Quality System include the Data Quality Objectives Process, Quality Assurance Project Plans, Standard Operating Procedures, Technical Assessments, and Data Quality Assessment.

At the management level, the **Quality System** requires that organizations prepare **Quality Management Plan** (QMP). The QMP provides an overview of responsibilities and lines of authority with regards to quality issues within an organization.

Organizations with **QMPs** review their own performance and develop **Quality Assurance Annual Report and Work Plans** (QAARWP) that provide information on the previous year's QA/QC activities and those planned for the current year. The QAARWP functions as an important management tool at the organizational level as well as at the Agency-wide level when QAARWP supplied information is compiled across organizations.

At longer multi-year intervals EPA conducts periodic **Management System Reviews** for organizations. An **MSR** consists of a site visit; a draft report that details findings and recommended corrective actions, consideration of the reviewed organization's formal response to the draft report and the authoring of a final report.

At the project level, the data life cycle of planning, implementation and assessment becomes important. The data life cycle begins with systematic planning. EPA recommends that this required planning be conducted using the **Data Quality Objectives (DQO) Process**.

The **Quality Assurance Project Plan (QAPP)** is the principal output of the **DQO** process and is the project-specific blueprint for obtaining data appropriate for decision-making. The QAPP translates the DQOs into performance specifications and QA/QC procedures for the data collectors.

The final step in the data life cycle is the **Data Quality Assessment (DQA)** which determines whether the acquired data meet the assumptions and objectives of the systematic planning process which resulted in their collection. In other words, the DQA determines whether the data are usable because they are of the quantity and quality required to support Agency decisions.